[redacted]

510(K) SUMMARY

NOV 16 2012

Submitter Information

Submitter's Name:	Incite Innovation LLC
Address:	P.O. Box 15388 1500 Main Street, Ste 2410 Springfield, MA 01115-5707
Telephone:	413-382-0212
Contact Person:	John Kirwan

Date Prepared:	October 22, 2012
Device Trade Name:	Incite Anchored Cervical Interbody Fusion (ACI) Device
Common/Usual Name:	Spinal Intervertebral body fixation orthosis
Classification:	21 CFR §888.3080
Class:	II
Product Code:	OVE

Predicate Devices:

LDR Spine - Cervical Interbody Fusion System, ROI-C, K091088

Zimmer Spine - BAK/Cervical (BAK/C®) Interbody Fusion System, P984008

Intended Use:

The Incite Anchored Cervical Interbody Device is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Incite Anchored Cervical Interbody Device is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental fixation, i.e. an anterior cervical plate, is required to properly utilize this system.

Device Description:
The Incite Anchored Cervical Interbody Fusion Device acts as a spacer to maintain proper Intervertebral and vertebral body spacing and angulation. The Incite Anchored Cervical Interbody Fusion Device is manufactured from PEEK and Ti6Al4V titanium alloy with tantalum radiopaque markers.

Predicate Device(s):
The Incite Anchored Cervical Interbody Fusion Device was shown to be substantially equivalent to previously cleared devices and had the same indications for use, design, function, and materials used.

Performance Testing:
Testing performed on this device indicates that the Incite Anchored Cervical Interbody Fusion Device is substantially equivalent to predicate devices and suitable for its intended use. Testing performed includes:

- Axial Compression – Static and Dynamic per ASTM F2077
- Compression-Shear – Static and Dynamic per ASTM F2077
- Torsion – Static and Dynamic per ASTM F2077
- Subsidence per ASTM 2267
- Expulsion per ASTM Draft F04.25.0202
- Cadaver Lab

Substantial Equivalence:
When considering indications for use, design, materials, and function the Incite Anchored Cervical Interbody Fusion Device was shown to be substantially equivalent to previously cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Incite Innovation, LLC
% Mr. John Kirwan
President
1500 Main Street, Suite 2410
Springfield, Massachusetts 01115

Letter Dated: November 16, 2012

Re: K122008
Trade Name: Incite Anchored Cervical Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: November 7, 2012
Received: November 8, 2012

Dear Mr. Kirwan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Laurence D. Coyne

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K122008

The Incite Anchored Cervical Interbody Device is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The Incite Anchored Cervical Interbody Device is to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental fixation, i.e. an anterior cervical plate, is required to properly utilize this system.

Prescription Use ___X___	AND/OR	Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122008